



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0007]

Prescription Drug User Fee Rates for Fiscal Year 2017

AGENCY: Food and Drug Administration, HHS

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for prescription drug user fees for fiscal year (FY) 2017. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Prescription Drug User Fee Amendments of 2012 (PDUFA V), authorizes FDA to collect user fees for certain applications for the review of human drug and biological products, on establishments where the products are made, and on such products. This notice establishes the fee rates for FY 2017.

FOR FURTHER INFORMATION CONTACT: Robert J. Marcarelli, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE-14202F, Silver Spring, MD 20993-0002, 301-796-7223.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 735 and 736 of the FD&C Act (21 U.S.C. 379g and 379h, respectively) establish three different kinds of user fees. Fees are assessed on the following: (1) Certain types of applications and supplements for the review of human drug and biological products; (2) certain establishments where such products are made; and (3) certain products (section 736(a) of the

FD&C Act). When certain conditions are met, FDA may waive or reduce fees (section 736(d) of the FD&C Act).

For FY 2013 through FY 2017, the base revenue amounts for the total revenues from all PDUFA fees are established by PDUFA V. The base revenue amount for FY 2013, which became the base amount for the remaining four FYs of PDUFA V, is \$718,669,000, as published in the **Federal Register** of August 1, 2012 (77 FR 45639). The FY 2013 base revenue amount is further adjusted each year after FY 2013 for inflation and workload. For FY 2017, fee revenue and fees may be further adjusted by the final year adjustment. In addition, for FY 2017, excess collections are offset as required by the FD&C Act. Fees for applications, establishments, and products are to be established each year by FDA so that revenues from each category will provide one-third of the total revenue to be collected each year.

This document provides fee rates for FY 2017 for an application requiring clinical data (\$2,038,100), for an application not requiring clinical data or a supplement requiring clinical data (\$1,019,050), for an establishment (\$512,200), and for a product (\$97,750). These fees are effective on October 1, 2016, and will remain in effect through September 30, 2017. For applications and supplements that are submitted on or after October 1, 2016, the new fee schedule must be used. Invoices for establishment and product fees for FY 2017 will be issued in August 2016 using the new fee schedule.

II. Fee Revenue Amount for FY 2017

The base revenue amount for FY 2017 is \$718,669,000 prior to adjustments for inflation, workload, the offset of excess collections, and the final year adjustment (see sections 736(c)(1), 736(c)(2), 736(g)(4), and 736(c)(3) of the FD&C Act, respectively).

A. FY 2017 Statutory Fee Revenue Adjustments for Inflation

PDUFA V specifies that the \$718,669,000 is to be further adjusted for inflation increases for FY 2017 using two separate adjustments--one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 736(c)(1) of the FD&C Act).

The component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all PC&B paid per full-time equivalent (FTE) position at FDA for the first three of the preceding four FYs, multiplied by the proportion of PC&B costs to total FDA costs of process for the review of human drug applications for the first three of the preceding four FYs (see section 736(c)(1)(A) and (c)(1)(B) of the FD&C Act).

Table 1 summarizes that actual cost and FTE data for the specified FYs, and provides the percent changes from the previous FYs and the average percent changes over the first three of the four FYs preceding FY 2017. The 3-year average is 1.8759 percent.

Table 1.--FDA Personnel Compensation and Benefits (PC&B) Each Year and Percent Changes

Fiscal Year	2013	2014	2015	3-Year Average
Total PC&B	\$1,927,703,000	\$2,054,937,000	\$2,232,304,000	
Total FTE	13,974	14,555	15,484	
PC&B per FTE	\$137,949	\$141,184	\$144,168	
Percent Change From Previous Year	1.1690%	2.3451%	2.1136%	1.8759%

The statute specifies that this 1.8759 percent should be multiplied by the proportion of PC&B costs to total FDA costs of the process for the review of human drug applications. Table 2 shows the PC&B and the total obligations for the process for the review of human drug applications for three FYs.

Table 2.--PC&B as a Percent of Fee Revenues Spent on the Process for the Review of Human Drug Applications

Fiscal Year	2013	2014	2015	3-Year Average
Total PC&B	\$568,206,210	\$585,260,720	\$615,483,892	
Total Costs	\$966,169,007	\$1,077,263,695	\$1,127,664,528	
PC&B Percent	58.8102%	54.3285%	54.5804%	55.9064%

The payroll adjustment is 1.8759 percent from table 1 multiplied by 55.9064 percent (or 1.0487 percent).

The statute specifies that the portion of the inflation adjustment for non-payroll costs is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Baltimore, DC-MD-VA-WV; not seasonally adjusted; all items; annual index) for the first three years of the preceding four years of available data multiplied by the proportion of all costs other than PC&B costs to total costs of the process for the review of human drug applications for the first three years of the preceding four FYs (see section 736(c)(1)(C) of the FD&C Act). Table 3 provides the summary data for the percent changes in the specified CPI for the Washington-Baltimore area. The data are published by the Bureau of Labor Statistics and can be found on its Web site at: <http://data.bls.gov/cgi-bin/surveymost?cu>. The data can be viewed by checking the box marked “Washington-Baltimore All Items, November 1996=100 - CUURA311SA0” and then selecting “Retrieve Data”.

Table 3.--Annual and 3-Year Average Percent Change in CPI for Washington-Baltimore Area

Year	2013	2014	2015	3-Year Average
Annual CPI	152.500	154.847	155.353	
Annual Percent Change	1.5232%	1.5390%	0.3268%	1.1297%

To calculate the inflation adjustment for non-payroll costs, we multiply the 1.1297 percent by the proportion of all costs other than PC&B to total costs of the process for the review of human drug applications obligated. Since 55.9064 percent was obligated for PC&B as shown in Table 2, 44.0936 percent is the portion of costs other than PC&B (100 percent minus 55.9064 percent equals 44.0936 percent). The non-payroll adjustment is 1.1297 percent times 44.0936 percent, or 0.4981 percent.

Next, we add the payroll adjustment (1.0487 percent) to the non-payroll adjustment (0.4981 percent), for a total inflation adjustment of 1.5468 percent (rounded) for FY 2017.

PDUFA V provides for this inflation adjustment to be compounded after FY 2013 (see section 736(c)(1) of the FD&C Act). This factor for FY 2017 (1.5468 percent) is compounded by adding one and then multiplying by one plus the compound inflation adjustment factor for FY 2016 (6.4414 percent), as published in the **Federal Register** of August 3, 2015 (80 FR 46028 at 46032), which equals to 1.080878 (rounded) (1.015468×1.064414) for FY 2017. We then multiply the base revenue amount for FY 2017 (\$718,669,000) by 1.080878, yielding an inflation-adjusted amount of \$776,793,511.

B. FY 2017 Statutory Fee Revenue Adjustments for Workload

The statute specifies that after the \$718,669,000 has been adjusted for inflation, the inflation-adjusted amount shall be further adjusted for workload (see section 736(c)(2) of the FD&C Act).

To calculate the FY 2017 workload adjustment, FDA calculated the average number of each of the four types of applications specified in the workload adjustment provision: (1) Human drug applications; (2) active commercial investigational new drug applications (INDs) (applications that have at least one submission during the previous 12 months); (3) efficacy supplements; and (4) manufacturing supplements received over the 3-year period that ended on June 30, 2012 (base years), and the average number of each of these types of applications over the most recent 3-year period that ended June 30, 2016.

The calculations are summarized in table 4. The 3-year averages for each application category are provided in column 1 (“3-Year Average Base Years 2010-2012”) and column 2 (“3-Year Average 2014-2016”). Column 3 reflects the percent change in workload from column 1 to column 2. Column 4 shows the weighting factor for each type of application, estimating how much of the total FDA drug review workload was accounted for by each type of application in

the table during the most recent 3 years. Column 5 is the weighted percent change in each category of workload. This was derived by multiplying the weighting factor in each line in column 4 by the percent change from the base years in column 3. The values in column 5 are summed, reflecting an increase in workload of 13.1047 percent (rounded) for FY 2017 when compared to the base years.

Table 4.--Workload Adjuster Calculation for FY 2017

Application Type	Column 1 3-Year Average Base Years 2010-2012	Column 2 3-Year Average 2014-2016	Column 3 Percent Change (Column 1 to Column 2)	Column 4 Weighting Factor (percent)	Column 5 Weighted Percent Change
New Drug Applications/Biologics License Applications	124.3000	147.3000	18.5036	35.8514	6.6338
Active Commercial INDs	6830.0000	7598.0000	11.2445	41.0966	4.6211
Efficacy Supplements	136.3000	196.3000	44.0205	6.8122	2.9988
Manufacturing Supplements	2548.3000	2368.0000	-7.0753	16.2399	-1.1490
FY 2017 Workload Adjuster					13.1047

Table 5 shows the calculation of the inflation and workload adjusted amount for FY 2017. The \$718,669,000 subject to adjustment on line 1 is multiplied by the inflation adjustment factor of 1.080878, resulting in the inflation-adjusted amount on line 3, \$776,793,511. That amount is then multiplied by one plus the workload adjustment of 13.1047 percent on line 4, resulting in the inflation and workload adjusted amount of \$878,590,000 on line 5, rounded to the nearest thousand dollars.

Table 5.--PDUFA Inflation and Workload Adjusted Amount for FY 2017, Summary Calculation

FY 2013 Revenue Amount and Base Subsequent FYs as published in the <u>Federal Register</u> of August 1, 2012 (77 FR 45639) (rounded to nearest thousand dollars)	\$718,669,000	Line 1
Inflation Adjustment Factor for FY 2017 (1 plus 8.0878 percent)	1.080878	Line 2
Inflation Adjusted Amount	\$776,793,511	Line 3
Workload Adjustment Factor for FY 2017 (1 plus 13.1047 percent)	1.131047	Line 4
Inflation and Workload Adjusted Amount (rounded to nearest thousand dollars)	\$878,590,000	Line 5

III. Offset for Excess Collections Through FY 2016

Under the provisions of the FD&C Act, if the sum of the cumulative amount of the fees collected for FY 2013 through 2015, and the amount of fees estimated to be collected under this

section for FY 2016, exceeds the cumulative amount appropriated for fees for FYs 2013 through 2016, the excess shall be credited to FDA's appropriation account and subtracted from the amount of fees that FDA would otherwise be authorized to collect for FY 2017 under the FD&C Act (see section 736(g)(4) of the FD&C Act as amended by PDUFA V).

Table 6 shows the amounts specified in appropriation acts for each year from FY 2013 through FY 2016, and the amounts FDA has collected for FYs 2013, 2014, and 2015 as of June 30, 2016, and an additional \$70,907,000 (rounded to the nearest thousand dollars) that FDA estimates it will collect in FY 2016 based on historical data. Table 6 shows the estimated cumulative difference between PDUFA fee amounts specified in appropriation acts for FY 2013 through FY 2016 and PDUFA fee amounts collected.

Table 6--Offsets To be Taken for PDUFA V

Fiscal Year	Collections Realized	Collection Amount Specified in Appropriation Acts	Amount in Excess of Collection Amount Specified in Appropriation Acts
2013	\$721,224,494	\$718,669,000	\$2,555,494
2014	\$805,856,366	\$760,000,000	\$45,856,366
2015	\$852,746,867	\$798,000,000	\$54,746,867
2016	\$872,388,000	\$851,481,000	\$20,907,000
Net Balance to be Offset When Fees are Set for FY 2017			\$124,065,726

Note: FY 2016 'Collections Realized' is the amount FDA estimates it will collect in FY 2016 based on historical data.

The cumulative fees collected for FYs 2013 through 2016 are estimated to be \$124,065,726 greater than the cumulative fee amounts specified in appropriation acts during this same period. Reducing the inflation and workload adjusted amount of \$878,590,000 by the PDUFA V offset of \$124,066,000 (rounded to the nearest thousand dollars) results in an amount of \$754,524,000, before the final year adjustment.

IV. Final Year Adjustment

Under the provisions of the FD&C Act, as amended, for FY 2017 the Secretary of Health and Human Services may, in addition to the inflation and workload adjustments, further increase

the fees and fee revenues if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for the process for the review of human drug applications for the first 3 months of FY 2018. If such an adjustment is necessary, the rationale for the amount of this increase shall be contained in the annual notice establishing fee revenues and fees for FY 2017 (see section 736(c)(3) of the FD&C Act).

After running analyses on the status of PDUFA's operating reserves and its estimated balance as of the beginning of FY 2018, FDA estimates that the PDUFA program will have sufficient funds for the operating reserves, thus FDA will not be performing a final year adjustment for FY 2018 because FDA has determined such an adjustment to be unnecessary.

The FD&C Act specifies that one-third of the total fee revenue is to be derived from application fees, one-third from establishment fees, and one-third from product fees (see section 736(b)(2) of the FD&C Act). Accordingly, one-third of the total revenue amount (\$754,524,000), or a total of \$251,508,000, is the amount of fee revenue that will be derived from each fee type: Application fees, establishment fees, and product fees.

V. Application Fee Calculations

A. Application Fee Revenues and Application Fees

Application fees will be set to generate one-third of the total fee revenue amount, or \$251,508,000 in FY 2017.

B. Estimate of the Number of Fee-Paying Applications and Setting the Application Fees

For FY 2013 through FY 2017, FDA will estimate the total number of fee-paying full application equivalents (FAEs) it expects to receive the next FY by averaging the number of fee-paying FAEs received in the three most recently completed FYs. Beginning with FY 2016, prior

year FAE totals will be updated annually to reflect refunds and waivers processed after the close of the FY.

In estimating the number of fee-paying FAEs, a full application requiring clinical data counts as one FAE. An application not requiring clinical data counts as one-half of an FAE, as does a supplement requiring clinical data. An application that is withdrawn, or refused for filing, counts as one-fourth of an FAE if the applicant initially paid a full application fee, or one-eighth of an FAE if the applicant initially paid one-half of the full application fee amount.

As table 7 shows, the average number of fee-paying FAEs received annually in the most recent 3-year period is 123.405 FAEs. FDA will set fees for FY 2017 based on this estimate as the number of full application equivalents that will pay fees.

Table 7.--Fee-Paying FAEs

FY	2013	2014	2015	3-Year Average
Fee-Paying FAEs	109.010	128.750	132.456	123.405

Note: Beginning with FY 2016, prior year FAE totals will be updated annually to reflect refunds and waivers processed after the close of the FY.

The FY 2017 application fee is estimated by dividing the average number of full applications that paid fees over the latest 3 years, 123.405, into the fee revenue amount to be derived from application fees in FY 2017, \$251,508,000. The result, rounded to the nearest hundred dollars, is a fee of \$2,038,100 per full application requiring clinical data, and \$1,019,050 per application not requiring clinical data or per supplement requiring clinical data.

VI. Fee Calculations for Establishment and Product Fees

A. Establishment Fees

At the beginning of FY 2016, the establishment fee was based on an estimate that 485 establishments would be subject to and would pay fees. By the end of FY 2016, FDA estimates that 523 establishments will have been billed for establishment fees, before all decisions on requests for waivers or reductions are made. FDA estimates that a total of 16 establishment fee

waivers or reductions will be made for FY 2016. In addition, FDA estimates that another 16 full establishment fees will be exempted this year based on the orphan drug exemption in section 736(k) of the FD&C Act. Subtracting 32 establishments (16 waivers, plus the estimated 16 establishments under the orphan exemption) from 523 leaves a net of 491 fee-paying establishments. FDA will use 491 to estimate the FY 2017 establishments paying fees. The fee per establishment is determined by dividing the adjusted total fee revenue to be derived from establishments (\$251,508,000) by the estimated 491 establishments, for an establishment fee rate for FY 2017 of \$512,200 (rounded to the nearest hundred dollars).

B. Product Fees

At the beginning of FY 2016, the product fee was based on an estimate that 2,480 products would be subject to and would pay product fees. By the end of FY 2016, FDA estimates that 2,646 products will have been billed for product fees, before all decisions on requests for waivers, reductions, or exemptions are made. FDA assumes that there will be 41 waivers and reductions granted. In addition, FDA estimates that another 32 product fees will be exempted this year based on the orphan drug exemption in section 736(k) of the FD&C Act. FDA estimates that 2,573 products will qualify for and pay product fees in FY 2016, after allowing for an estimated 73 waivers and reductions, including the orphan drug products, and will use this number for its FY 2017 estimate. The FY 2017 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees (\$251,508,000) by the estimated 2,573 products for a FY 2017 product fee of \$97,750 (rounded to the nearest ten dollars).

VII. Fee Schedule for FY 2017

The fee rates for FY 2017 are displayed in table 8:

Table 8.--Fee Schedule for FY 2017

Fee Category	Fee Rates for FY 2017
Applications	
Requiring clinical data	\$2,038,100
Not requiring clinical data	\$1,019,050
Supplements requiring clinical data	\$1,019,050
Establishments	\$512,200
Products	\$97,750

VIII. Fee Payment Options and Procedures

A. Application Fees

The appropriate application fee established in the new fee schedule must be paid for any application or supplement subject to fees under PDUFA that is received on or after October 1, 2016. Payment must be made in U.S. currency by electronic check, check, bank draft, wire transfer, or U.S. postal money order payable to the order of the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at <https://userfees.fda.gov/pay>. Once you search for your invoice, click “Pay Now” to be redirected to Pay.gov. Note that electronic payment options are based on the balance due. Payment by credit card is available for balances less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be drawn on U.S bank accounts as well as U.S. credit cards.

FDA has partnered with the U.S. Department of the Treasury to use Pay.gov, a Web-based payment application, for online electronic payment. The Pay.gov feature is available on the FDA Web site after the user fee ID number is generated.

Please include the user fee identification (ID) number on your check, bank draft, or postal money order. Your payment can be mailed to: Food and Drug Administration, P.O. Box 979107, St. Louis, MO 63197-9000.

If checks are to be sent by a courier that requests a street address, the courier can deliver the checks to: U.S. Bank, Attention: Government Lockbox 979107, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery contact the U.S. Bank at 314-418-4013. This telephone number is only for questions about courier delivery).

Please make sure that the FDA post office box number (P.O. Box 979107) is written on the check, bank draft, or postal money order.

If paying by wire transfer, please reference your unique user fee ID number when completing your transfer. The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the fee and add it to your payment to ensure that your fee is fully paid. The account information for wire transfers is as follows: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., 14th Floor, Silver Spring, MD 20993-0002.

The tax identification number of FDA is 53-0196965.

B. Establishment and Product Fees

FDA will issue invoices for establishment and product fees for FY 2017 under the new fee schedule in August 2016. Payment will be due on October 1, 2016. FDA will issue invoices in November 2017 for any products and establishments subject to fees for FY 2017 that qualify for fee assessments after the August 2016 billing.

Dated: July 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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